

Serial No.: 09/340,338
Group Art Unit: 1615

Remarks

This Amendment is responsive to the Office Action mailed November 5, 2002 (Paper No. 23). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Assuming entry of the amendments set forth in this Paper, the status of the claims is as follows:

Amended:	
Cancelled:	1, 3-5, 7-23, 26-36 and 39-41
New:	42-103
Pending:	42-103

Claims

Claims 1, 3-5, 7-23, 26-36 and 39-41 were pending. Claims 1, 3-5, 7-23, 26-36 and 49-41 stood rejected.

Claims 1, 3-5, 7-23, 26-36 and 39-41 have been cancelled without prejudice or disclaimer of the subject matter contained therein.

New claims 42-103 have been added to more clearly define the invention. No new matter is added.

It is believed that entry of this amendment will require payment of additional claim fees. Applicant hereby authorizes the commissioner to charge the additional claim fees required for consideration of this amendment to Deposit Account No. 04-0480.

Support

Support for the new claims is either apparent or as set forth herein. Specifically, support for the recitation, "wherein the device does not comprise a backing layer and wherein the device does not comprise a release liner" may be found in the specification at, for example, page 7, lines 3-4. Support for the recitation "wherein the therapeutic agent is misoprostol" may be found in the specification at, for example, page 5, line 6. Support for the recitation "wherein the disk comprises 70 to 95 wt% filmogenic polymer" may be found in the specification at, for example, page 9, lines 28-29. Support for the recitation "mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone" may be found in the specification at, for example, page 7, lines 1-2.

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Support for the recitation “placing the device in contact with the wetted surface, thereby wetting the disk and delivering the at least one therapeutic agent” may be found in the specification at, for example, page 7, lines 4-8. No new matter is added.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 3-5, 7-8, 13, 18-23, 27, 36 and 39-41 stood rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,007,836 ('836). Specifically, the Examiner asserts that

'836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). The compositions of '836 produce an erection “on demand, immediately before sexual intercourse” and are therefore thought to be released in less than one hour. Furthermore, '836 discloses “anchoring the transdermal patch to the skin of the user” (C 8, L 2-4). It is the position of the examiner that this meets the instant requirement that the patch is rigid, since the specification does not appear to provide a clear indication of what is meant by the word “rigid” in the instant claims. Therefore, Webster’s New World Dictionary (1988), which defines rigid as “not moving; firmly fixed,” is relied upon to provide the meaning of the term.

Applicant’s arguments filed 8-5-02 have been fully considered but they are not persuasive.

Applicant argues that the instant claims are allowable over '836 on the basis that the instant claims require the disc to be “rigid.” This is not found persuasive. The instant specification does not appear to provide a clear indication of the meaning of the term. Accordingly, Webster’s New World Dictionary (1988) is relied upon to provide the meaning of the term. Page 1156 of Webster’s defines rigid as “not moving; firmly fixed.” '836 appears to meet this definition in column 8, lines 3-4 where it discloses “anchoring the transdermal patch to the skin of the user.” Accordingly, it is the position of the examiner that '836 meets the requirement that the patch is rigid. The instant claims have also been amended to recite “consisting essentially of” transitional language regarding the filmogenic polymer. For purposes of searching for and applying prior art, “consisting essentially of” is construed as equivalent to “comprising” and the burden is upon applicant to show that the introduction of additional steps or

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components would materially change the characteristics of applicant's invention (MPEP 2111.03 and *In re Janakirama-Rao* 137 USPQ 893).

Applicant argues that the instant claims are allowable over '836 since '836 requires an adhesive, while the instant claims do not encompass devices having an adhesive. However, this argument is not persuasive since the claims recite comprising as the transitional phrase. Therefore, the claims are still not closed as the claims "further comprise" ingredients including a stabilizer, a solubilizer, an enhancer, and a plasticizer. Adhesives fall within these ingredients. Furthermore, one would look to the specification to understand what the disk of the instant claims is. There, one finds that the specification discloses that the disk comprises adhesives.

Applicants respectfully disagree. Notwithstanding, to expedite prosecution, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection.

Applicants respectfully note that new claims 42-56, 76-79 and 86-101 are directed to devices, which, *inter alia*, specifically exclude the use of a release liner and a backing layer, and methods of using such devices. The '836 patent does not disclose such a device or their use. To the contrary, the '836 patent discloses devices which specifically require the use of a release liner and a backing layer. (See, e.g., Col. 7, lines 41-43 & 56-63).

Applicants further note that new claims 57-75 and 80-85 are directed to devices, which, *inter alia*, specifically comprise 70 to 95 wt% or 90 to 95 wt% filmogenic polymer, and methods of using such devices. The '836 patent does not disclose a device comprising either 70 to 95 wt% or 90 to 95 wt% filmogenic polymer.

Reconsideration and withdrawal of this rejection in view of the foregoing are respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 3-5, 7-8, 13, 17-23, 26-27, 29, 34-36 and 39-41 stood rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,007,836 ('836). Specifically, the Examiner asserts that

'836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a

combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). '836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort to increase or decrease flexibility of the polymer film. The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 does not state whether the penile surface requires pre-wetting. It is submitted that since it not say that wetting the surface is require, no pre-wetting is necessary. It is also submitted that pre-wetting the surface would be obvious to one skilled in the art at the time of the invention to aid in adhesion of the patch to the skin, since this would aid in creating a vacuum. '836 also discloses "anchoring the transdermal patch to the skin of the user" (C 8, L 3-4). It is the position of the examiner that this meets the instant requirement that the patch is rigid, since the specification does not appear to provide a clear indication of what is meant by the word "rigid" in the instant claims. Therefore, Webster's New World Dictionary (1988), which defines rigid as "not moving; firmly fixed," is relied upon to provide the meaning of the term.

Applicants respectfully disagree. Notwithstanding, to expedite prosecution, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection.

Applicants respectfully note that the '836 patent specifically teaches away from the devices as claimed in new claims 42-56, 76-79 and 86-101. That is, the '836 patent specifically teaches that

[t]o protect the inner layer of adhesive prior to the application of the patch, all the embodiments are provided with a **release liner**.

(See '836 Col. 7, lines 41-43)(emphasis added). The '836 patent further specifically teaches that

[a]ll of the non-condom embodiments are constructed with at least one outer, stretchable, impermeable barrier layer composed of polyvinyl, polyethylene, polyester or aluminized polymer films and composite films, or any other suitable, **impermeable**, stretchable and flexible material. The at least one outer layer extends beyond the perimeter of the underlying layers, and has an adhesive material on the inner surface.

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(See '836 Col. 7, lines 56-63)(emphasis added). Hence, the '836 patent specifically teaches the use of both a baking layer and a release liner in all of its non-condom embodiments.

Moreover, the '836 patent does not disclose or suggest that it would be advantageous to provide a device having a filmogenic polymer content of either 70 to 95 wt% or 90 to 95 wt%.

Reconsideration and withdrawal of this rejection in view of the foregoing are respectfully requested.

Claims 1, 3-5, 7-14, 17-23, 26-30, 34-36 and 39-41 stood rejected under 35 U.S.C. § 103 as unpatentable over a combination of '836 and U.S. Patent No. 4,969,821 ('821). Specifically, the Examiner asserts that

'836 is relied upon for all that it teaches as stated previously.

'821 is relied upon for teaching that polyvinylpyrrolidone film is an effective means for controlling the release of an active agent when administered transdermally. '821 also teaches the inclusion of plasticizers in the polyvinylpyrrolidone films wherein the plasticizer is PEG 400. The amount of plasticizer is unclear since '821 teaches weight per volume of liquid. Should applicants traverse on the grounds that the amount of plasticizer of '821 is outside the instant ranges, applicants are requested to submit evidence pertaining thereto. Furthermore, it is submitted that the ranges pertaining to the amount of plasticizer is a manipulatable parameter and it would be obvious to one skilled in the art at the time of the invention to adjust the amount of plasticizer in the composition to increase or decrease the flexibility of the film.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of the '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

Applicants respectfully traverse. For, *inter alia*, the reasons set forth above regarding the '836 patent, the subject combination fails to disclose, teach or suggest the claimed invention.

Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1, 3-5, 7-8, 13, 15-23, 26-27, 29, 31-36 and 39-41 stood rejected under 35 U.S.C. § 103 as unpatentable over a combination of '836 and FR 2710649. Specifically, the Examiner asserts that

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'836 is relied upon for all that it teaches as stated previously.

'649 is relied upon for teaching transdermal films formulated as a biodegradable patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the polymer films of '836 from gliadin with the motivation to provide a transdermal patch to treat impotence that is biodegradable and the expectation that gliadin transdermal patches are biodegradable.

Applicants respectfully traverse. For, *inter alia*, the reasons set forth above regarding the '836 patent, the subject combination fails to disclose, teach or suggest the claimed invention.

Reconsideration and withdrawal of this rejection are respectfully requested.

FEE DEFICIENCY

- ☒ This Paper is believed timely filed with a one (1) month extension of time. If an additional extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.

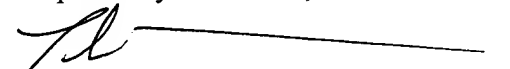
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- ☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

Closing Remarks

Applicant thanks the Examiner for the Office Action and believes this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,


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